Proposed Re-evaluation Decision PRVD2017-05

E-8-dodecenyl acetate, Z–8-dodecenol and Z–8–dodecenyl acetate

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of the pesticide products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate for sale and use in Canada.

An evaluation of available scientific information has found that products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate do not present unacceptable risks to human health or the environment when used according to the label directions. This proposal affects all pesticide products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate registered in Canada.

This Proposed Re-evaluation Decision (PRVD) is a consultation document[1] that summarizes the science evaluation for E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The Overview describes the regulatory process and key points of the re-evaluation, while the Science Evaluation provides detailed technical information on the assessment of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What are E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate?

E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are straight-chained lepidopteran pheromones (SCLP). They are co-formulated and registered for the control of oriental fruit moth, lesser apple worm and codling moth in fruits. The products are packaged as slow-release generator devices, or in cartridges for automated aerosol dispensers, that are placed in the tree canopy.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

Health Considerations

Can Approved Uses of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate Affect Human Health?

E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are unlikely to affect your health when used according to the label directions.

People could be exposed to E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate by working as a loader/applicator, by entering treated sites.

Occupational exposures of the workers loading and applying the products by placing the generator devices or cartridges in the tree canopy as well as the workers re-entering treated sites, are not of concern under current conditions of use. As a result of the low toxicity of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate, and use at levels which are not expected to be significantly greater than the background natural concentration of these pheromones, bystander exposure is not expected to be of concern. The dietary risks of the active ingredients from food and drinking water are expected to be negligible given the low toxicity and the low exposure.

Environmental Considerations

What Happens When E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate Are Introduced Into the Environment?

E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are used at levels similar to naturally occurring concentrations of these pheromones. The exposure to the environment is very limited, when used as directed on the label. There is minimal risk from these actives to mammals, birds, and aquatic organisms. The environment exposure is not expected to be of concern.

Measures to Minimize Risk

Labels of registered pesticide products include instructions for use. The directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. No additional mitigation measures or label updates are proposed as a result of the re-evaluation.

What Additional Scientific Information is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

In Canada, the re-evaluations of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate were initiated on 9 September 2015. Currently registered products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are listed in Appendix I.

2.0 Use Description of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate

E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are straight-chained lepidopteran pheromones (SCLP). The three active ingredients are co-formulated together in end-use products which are registered for use as behavioral mating disruptors on oriental fruit moth, lesser apple worm and codling moth in the trees of pome fruit, stone fruit, walnuts and butternut. These products are packaged as slow-release generator devices or in cartridges for automated aerosol dispensers, which are then placed in lateral branches of the upper tree canopy. They can be applied at rates range from 43 to 459 g a.i. /ha. As of 1 May, 2017, a total of eight products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are registered in Canada (three technical and five commercial end-use products).

3.0 The Technical Grade Active Ingredients and Their Properties

3.1 Identity of the Technical Grade Active Ingredients

Common Name		**E-8-dodecenyl acetate**	**Z-8-dodecenol**	**Z-8-dodecenyl acetate**
Function		pheromone	pheromone	pheromone
Chemical Name International Union of Pure and Applied Chemistry (IUPAC) Chemical Abstracts Service (CAS)		(8E)-DODEC-8-EN-1-YL ACETATE (E)-8-DODECENYL ACETATE	(8Z)-DODEC-8-EN-1-OL (Z)-8-DODECEN-1-OL	(8Z)-DODEC-8-EN-1-YL ACETATE (Z)-8-DODECENYL ACETATE
CAS Registry Number		38363-29-0	40642-40-8	28079-04-1
Purity of the Technical Grade Active Ingredient	**Registration Number**			
	26136	8%	1.3%	88%
	26982	5.91%	1.03%	92.01%
	29353	1.20%	0.23%	16.43%

4.0 Human Health

Exposure to the E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate may occur through consuming food and drinking water, working as a loader/applicator, or by entering treated sites.

4.1 Toxicological Summary

E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are of low acute toxicity by the oral, dermal and inhalation routes. No developmental or reproductive effects or evidence of carcinogenicity have been identified.

4.2 Occupational Exposure and Risk

Based on the high volatility and the rate of application being comparable to background levels of these pheromones, exposure to workers is expected to be minimal when used according to the current label directions, including use of required personal protective equipment. Exposure to E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate is not expected to be of concern. No additional mitigation measures are proposed.

4.3 Non-Occupational Exposure and Risk:

4.3.1 Dietary Exposure and Risk

Dietary exposure to E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate from food and drinking water is not expected to of concern given the pheromones are packaged in slow-release generators and are not applied directly to food crops or drinking water. Based on the low exposure potential and the low toxicity of the active ingredients, exposure is not expected to be of concern. No additional mitigation measures are proposed.

4.3.2 Residential and Bystander Exposure and Risk

There are no domestic class products registered. Residential exposure to E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate is not expected, based on the current use pattern. Based on the low toxicity of the actives, and the use at levels which are not significantly greater than the background concentrations, bystander exposure and risk is not also expected to be of concern.

4.4 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Because the dietary and residential exposure to E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate is low (Section 4.3.1 and 4.3.2), the aggregate exposure and risk is not expected to be of concern.

4.5 Cumulative Exposure and Risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA identified information indicating that E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate share a common mechanism of toxicity with other pest control products, specifically, SCLPs. However, because of the low toxicity of SCLPs to mammalian systems, the Agency does not expect any cumulative or incremental effects from exposure to residues of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate when used as directed on the label. Therefore, there is no requirement for a cumulative assessment at this time.

5.0 Environment

Environmental exposure is expected to be low based on the use of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate in Canada. The products are contained within canisters or dispensers which are manually attached to fruit trees. There is no broadcast or spray application of the actives into the environment. The active ingredients are released gradually into the environment and the exposure of these actives to the environment is expected to be very limited. Minimal risk from these compounds to mammals, birds, and aquatic organisms is expected. Based on the current use pattern, risks to the environment are considered to not be of concern.

6.0 Value

Pheromones such as mating disruptors are well suited to Integrated Pest Management (IPM) in crop production, because they are species specific and generally have no effect on non-target species. In IPM, these non-conventional products can also reduce the need for conventional insecticide treatments, thus reducing the exposure of pests to certain insecticides and possibly reducing the development of resistance.

Oriental fruit moth is an invasive species in Canada and presently found only in Southern Ontario where it is a serious pest of stone and pome fruits. Pheromones such as the mating disrupting products are a pest control option that can be used in a planned IPM to help control oriental fruit moth. Mating disruptors are recommended as an acceptable pest management option that can be used in organic apple production to target codling moth.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

Based on the available information, E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate do not meet TSMP Track 1 criteria as the active ingredients dissipate rapidly in the environment.

7.2 Contaminants of Health or Environmental Concern

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including Toxic Substances Management Policy (TSMP) Track 1 substances, are not expected to be present in the products.

8.0 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. As of 1 May, 2017, there are no incident reports of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate submitted to the PMRA.

9.0 Organisation for Economic Co-operation and Development Status of E–8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experience and seek solutions to common problems. As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl are currently acceptable for use in other OECD countries, including the United States, Australia and European Union Member States. As of 1 May 2017, no decision by an OECD member country to prohibit all uses of E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

The PMRA has determined that products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl for sale and use in Canada are acceptable for continued registration. No additional mitigation measures are required.

List of Abbreviations

a.i.	active ingredient
g	gram
ha	hectare
CAS	Chemical Abstracts Service
EED	E-8-dodecenyl acetate
IUPAC	International Union of Pure and Applied Chemistry
IPM	Integrated Pest Management
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
SCLP	straight-chained lepidopteran pheromones
TSMP	Toxic Substances Management Policy
ZAF	1-tetradecanol
ZAG	1-dodecanol
ZAH	(8E,10E)-8,10-dodecadien-1-ol) (Codlelure),
ZDD	Z-8-dodecenol
ZED	Z-8-dodecenyl acetate

Appendix I Registered products containing E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate as of 1 May, 2017.

Reg. No.	Product Name	Formulation	Class
26136	Bedoukian OFM Technical Pheromone	Liquid	Technical
26981*	Isomate-M100 Oriental Fruit Moth Pheromone	Slow-Release Generator	Commercial
26982	Oriental Fruit Moth Pheromone Technical	Liquid	Technical
27339*	Isomate-M Rosso Oriental Fruit Moth Pheromone	Slow-Release Generator	Commercial
29352	Isomate-CM/OFM TT	Device	Commercial
29353	CM/OFM TT Pheromone Technical	Liquid	Technical
31419	Isomate OFM TT	Slow-Release Generator	Commercial
31718	Semios OFM Plus	Pressurized Product	Commercial

* Discontinued. Expiration date is 2018-06-30.

References

Published Information

PMRA Document Number	Reference
2507028	PRO2002-02, Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals
655682	PRDD2003-06, Isomate-M 100 Oriental Fruit Moth Pheromone for use in Orchards to Disrupt Oriental Fruit Moth Mating
	REG2001-13, Isomate-M 100 Oriental Fruit Moth Pheromone for use in Orchards to Disrupt Oriental Fruit Moth Mating
	RDD2003-08, Isomate-M 100 Oriental Fruit Moth Pheremone
1771411	Evaluation Report for Application Number 2008-1295
1771455	Evaluation Report for Application Number 2008-1296
2292145	Evaluation Report for Application Number 2012-5701
2419990	Evaluation Report for Application Number 2013-7116
2495717	Evaluation Report for Application Number 2014-1774
	Isomate-C (Codling Moth Pheromone), PMRA (Environment Canada (E94-01, 30 March 1994))